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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,941	01/15/2002	Moira Marx Nir	01/22042	1504

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EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,941	NIR ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,13,16-29,35,42,45-60,65,72,75-85,150,151,153 and 158-163* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-4,13,16-29,35,42,45-60,65,72,75-85,150,151,153 and 158-163* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 08/22/2005 wherein claims 1, 13, 16, 20-24, 25, 26, 42, 45, 46, 51-55, 57, 72, 75, 76, 79, 80-84, 150, 153, 158, 159, 160, 162 and 163 have been amended, and claims 5-12, 14, 15, 30-34, 36-41, 43, 44, 61-64, 66-71, 73-74, 152 and 154-157 have been canceled.

Applicant's amendment by correcting the word "proceeds" in claim 162 has overcome the objection made in the office action dated 05/02/2005.

Applicant's amendment by adding "wherein silicone polymer comprises a cross-linked silicone polymer" is sufficient to overcome the rejection of claims 159-160 under 35 U.S.C. 112, second paragraph as being vague and indefinite.

Applicant's amendment that limits the independent claims 57, and 150 to skin or mucosal membrane ailment caused by HPV; to specific oxidizing agents, chlorinated isocyanurate; and specific biocompatible polymer, silicone polymer, and cancellation of claims 61-64, 66-71, 73-74, 152, and 154-157 is sufficient to overcome the rejection of claims under 35 U.S.C 112, first paragraph as failing to enable any person skilled in the art to use the invention commensurate in scope.

Applicant's amendment that limits the independent claim 150 to skin or mucosal membrane ailment caused by HPV, and cancellation of claims 152, and 154-156 is sufficient to overcome the rejection of claims 150-156 under 35 U.S.C. 102(b) as being anticipated by Boddie et al. (J. Dairy.Sci. 79, 1996, pages 1683-1688, of record in PTO-1449).

Applicant's amendment that limits the independent claims 26, 57, and 150 to skin or mucosal membrane ailment caused by HPV; to specific oxidizing agents, chlorinated isocyanurate; and specific biocompatible polymer, silicone polymer, and cancellation of claims 36-38, 61-64, 66-68, and 155-157 is sufficient to overcome the rejection of claims 26, 35-38, 57, 66-68, 150, and 155-157 under 35 U.S.C. 102(b) as being anticipated by Danner et al. (US 5,855,922, PTO-892 of record).

Applicant's amendment that limits the independent claims 1, 26, 57 to specific oxidizing agents, chlorinated isocyanurate; specific biocompatible polymer, silicone polymer; and to skin or mucosal membrane ailment caused by HPV, and cancellation of claims 5, 9-11, 30, 39-40, 61, 66-67, and 69-70 is sufficient to overcome the rejection of claims 1-5, 9-11, 26-30, 34-37, 39-40, 57-61, 65-67, and 69-70 under 35 U.S.C. 102(e) as being anticipated by Karagoezian (US 6,592,907, PTO-892 of record).

Applicant's amendment that limits the independent claims 1, 26, 57, and 150 to specific oxidizing agents, chlorinated isocyanurate; specific biocompatible polymer, silicone polymer; and to skin or mucosal membrane ailment caused by HPV, and cancellation of claims 5-11, 15, 30-34, 36-37, 39-40, 43, 44, 61-64, 66-67, 69-70, 74, and 152 is sufficient to overcome the rejection of claims 1-11, 15-37, 39-40, 44-67, 69-70, 74-85, 150-151, 155-156, and 158-163 under 35 U.S.C. 102(e) as being anticipated by Green (US 6,592,890, PTO-892 of record).

Applicant's amendment that limits the independent claims 26, and 57 to specific oxidizing agents, chlorinated isocyanurate; specific biocompatible polymer, silicone polymer; and to skin or mucosal membrane ailment caused by HPV, and cancellation of

claims 41, 43, 71, and 73 is sufficient to overcome the rejection of claims 41-43, and 71-73 under 35 U.S.C. 103(a) as being unpatentable over Green (US 6,592,890, PTO-892 of record), in view of Boddie et al.

Claims 1-4, 13, 16-29, 35, 42, 45-60, 65, 72, 75-85, 150-151, 153, 158-163 are pending, and examined herein.

Applicant's amendment necessitated the following new ground(s) of rejection presented in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-60, 72, 75-85, 150-151, 153, 158-163 contain the abbreviation or trademark/trade "HPV". Where a trademark or trade or abbreviation name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirement of 35 U.S.C. 112, second paragraph. See *Exparte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the abbreviation or trademark or trade name cannot be used properly to identify any particular material or product. A abbreviation or trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a abbreviation or trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the abbreviation trademark/trade name

or abbreviation is used to identify/describe particular virus, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 16-29, 35, 42, 45-56, 158-163 are rejected under 35 U.S.C. 102(b) as being anticipated by Pusineri et al (US 6,559,199, PTO-892).

Pusinari et al. discloses a composition comprising a silicone polymer and a antimicrobial agent, chlorinated isocyanurate being entrapped in or by silicone polymer for destroying microbes. Biocidal agents such as N-chloro derivatives of cyanuric acids, trichloroioscyanuric acid, sodium dichloroisocyanuric dihydrate are disclosed. See abstract; column 11, lines 44-46. The silicone polymers used have properties such as fluidity, film forming ability, paste type rheologies etc. See abstract; column 1, lines 5-10, lines 35-42, lines 63-65. The composition comprises polyorganosiloxane composition which can be crosslinked or which is in the form of a crosslinked elastomer, and a biocidal agent. The biocidal agents used are compounds which in the presence of water produce hypochlorous acid with high bactericidal capacity. See column 4, lines 10-17; column 11, lines 54-64. The biocides used have destructive properties towards

bacteria, viruses, fungi, yeast etc. See column 4, lines 34-37. It is also disclosed that the active substance such as biocide is incorporated inside the silicone matrix by homogenization. The composition can also comprise additives such as fillers, silicas, aluminas, sweeteners, saccharides etc. See column 12, lines 33-37, lines 49-54. The process for preparing the composition is also disclosed. The compositions can be crosslinked at room temperature i.e is room temperature vulcanization or by heat. See column 13-16; column 22, claim 6. It is also disclosed that the compositions are compatible for contact with the skin and mucous membrane. See column 3, lines 24-28. A composition comprising 20 parts by weight of bactericide is also disclosed. See column 14, line 51.

The recitation of the intended use of the claimed invention such as "for treating skin or mucosal membrane ailment caused by human papilloma virus" is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

It is well settled that "intended use" of a composition or product, e.g., "for treating skin or mucosal membrane ailment caused by human papilloma virus", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same compounds, silicone polymer, and chlorinated isocyanurate in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, Pusinari anticipates instant claims 1-4, 13, 16-29, 35, 42, 45-56, 158-163

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57-60, 65, 72, 75-85, 150-151, and 153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pusineri et al (US 6,559,199, PTO-892) as applied to claims 1-4, 13, 16-29, 35, 42, 45-56, 158-163 above, in view of Bosch (US 6,017,515, PTO-892).

Pusineri as discussed above teaches compositions comprising biocides, chlorinated isocyanurates in a silicone polymer. Additionally, Pusineri also teaches that the biocidal silicone elastomer, in particular of room temperature vulcanization is simple to obtain, is inexpensive, safe and compatible for contact with skin, is effective from the point of antiseptic activity, and posseses excellent physical and chemical properties. See column 3, lines 24-29, lines 52-56. Pusineri also teaches that such biocidal silicone compositions containing N-chlorinated compounds in the presence of water produce hypochlorous acid or salts of this acid such as NaOCl, which have high bactericidal activity. It is further taught that the biocides used have destructive properties towards bacteria, viruses, fungi, yeast etc. See column 4, lines 34-37

Pusineri does not specifically teach a method of treating skin ailment caused by human papilloma virus using a composition comprising chlorinated isocyanurate.

Bosch et al. (US 6,017,515) teaches a method of treating skin disorders and mucous membrane ailments caused by human papilloma viruses, such as for example warts comprising applying to the skin a composition comprising sodium hypochlorite, which is known to have bactericidal activity. See abstract; column 6, lines 40-46.

It would have been obvious to a person of ordinary skill in the art at the time of invention to use the biocidal composition comprising chlorinated isocyanurate in a silicone polymer taught by Pusineri for the treatment of skin ailments caused by virus such as warts. One ordinary skill in the art at the time of invention would have been motivated to use the composition taught by Pusineri for the treatment of warts because Pusineri teaches that the oxidizing agents, chlorine releasing compounds such as chlorinated isocyanurates are useful for treating diseases caused by viruses, fungi, bacteria etc., generally, and Bosch teaches that the chlorine releasing oxidizing agent, sodium hypochlorite is used in the treatment of warts caused by human papilloma virus. Thus one of ordinary skill in the art would have been motivated to use the biocidal silicone composition taught by Pusineri for skin ailment such as warts because the biocidal silicone composition taught by Pusineri on contact with water produces hypochlorous acid or salts of this acid such as NaOCl which are used in the treatment of warts.

Therefore, claims 57-60, 65, 72, 75-85, 150-151, and 153 are seen to be clearly obvious over the cited prior art.

Claims 57-60, 65, 72, and 75-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (US 6,592,890, PTO-892 of record), and further in view of Boddie at al. (J. Dairy Sci. 79, 1996, 1683-1688, PTO-1449 of record) and Bosch (US 6,017,515, PTO-892).

Green discloses a wound dressing composition having an anti-infective activity for treating skin ailments caused by microorganisms such as bacteria, comprising a sheet comprising a crosslinked polymer matrix, and oxidant generating formulation within or on the polymer matrix. Green also discloses that the oxidant generating formulation is stable at least until contacted by a substrate, such as glucose, which is permeable into the polymeric matrix from the patients body fluid. See column 4, lines 38-54; column 20, TABLE 3. It is also disclosed that the wound dressing can be a single sheet having the oxidant generating formulation, or plurality of staked sheets, having the same composition. See column 4, lines 56-65. The conformable, flexible, and spreadable polymers such as cross-linked polymers of polyacrylamide, polyurea, polyurethane, polyvinylchloride, polyesters, polymethyl methacrylate, polytetrafluorethylene, elastomeric organosilicon polymers etc., and combination thereof are disclosed. Hydrophobic polymers (elastomers) include such as medical grade Low Consistency Silicone elastomers such as NuSil MED-815, High consistency Silicone Elastomers suitable for extrusion such as NuSil MED-4550, as well as thermoplastic and room temperature vulcanization (RTV) silicone polymers. See column 11, lines 43-61.

Suitable anti-infective oxidizing agents disclosed are elemental iodine, hydrogen peroxide, hypohalites, hypothiocyanite etc. See column 14, lines 61-66. It is also disclosed that oxidizing agents hypohalites such as hypochlorites is formed upon wetting of the polymer in a body fluid. See column 15, lines 60-65. A 4 % by weight of oxidizing agent iodate in the composition is also disclosed. See column 21, lines 45-47. The data for anti-bacterial activity of oxidizing agent iodate in combination with iodide encapsulated Silicone patches is shown in column 19, TABLE 2. It is also disclosed that using a bilayer technique formulations of iodide and oxidizing agents of iodide can be encapsulated in a thin polymer comprising the upper layer, and this allows the sustained release of iodide and the oxidizing agent over extended period of time. See column 10, lines 8-15. Thus, the oxidizing agent is entrapped in the silicone polymer. It is further disclosed that the sponge like hydrogel composition containing oxidizing agent encapsulated in polymer can be fabricated into various shapes such as rolls, sheets etc. See column 12, lines 60-66. Disc shaped silicone devices containing the oxidizing agents in combination with NaCl were also prepared. See column 19, lines 20-23.

Green further teaches a method of preparing a pharmaceutical composition. Green teaches that finely ground oxidizing agent iodate and iodide were mixed into silicone elastomer and then the polymer was allowed to cure with dibutyl tin dilaurate catalyst. See column 17, EXAMPLE 1; column 19, lines 20-25; and column 21, EXAMPLE 3. A bilayer technique is also disclosed wherein the formulations of iodide and iodate, or other oxidizing agents of iodide are encapsulated in a thin polymer of polyurethane or

silicone comprising the upper layer, and combined with another film of polyurethane or silicone containing polymer. See column 10, lines 7-24.

Green does not teach the particular oxidizing agent, chlorinated isocyanurate entrapped in the silicone polymer.

Green does not teach a method of treating skin ailment caused by human papilloma virus using chlorinated isocyanurate entrapped in the silicone polymer.

Boddie et al. disclose the use of oxidizing agent comprising a chlorinated isocyanurate in a similar formulation and a method of treating teat skin infected by microorganisms using said formulation. Boddie teaches that teat dip formulations containing an oxidizing agent hypochlorous acid (a source of free chlorine), liberated from sodium dichloroisocyanurate in water by hydrolysis, were effective against bacteria such as *Staphylococcus aureus* and *Streptococcus agalactiae* IMI. See page 1683, column 2, lines 24-29. Bodie further teaches that sodium dichloroisocyanurate has a greater biocidal activity than sodium hypochlorite. See page 1686, left hand column bottom paragraph-right hand column, line 19.

Bosch et al. (US 6,017,515) teaches a method of treating skin disorders and mucous membrane ailments caused by viruses, such as for example warts comprising applying to the skin a composition comprising sodium hypochlorite. See abstract; column 6, lines 40-46.

It would have been obvious to a person of ordinary skill in the art at the time of invention to substitute oxidizing agent taught by Green by another oxidizing agent, chlorinated isocyanurate in the wound dressing composition of Green for treating skin

ailment because Boddie teaches teat dip formulation containing sodium isocyanurate for treating skin infections caused by bacteria.

It would have been obvious to a person of ordinary skill in the art at the time of invention to use a composition comprising oxidizing agent, chlorinated isocyanurate in a silicone polymer for the treatment of skin ailments caused by virus such as warts. because Bosch teaches that a oxidizing agent, sodium hypochlorite is used in the treatment of warts. One of ordinary skill in the art would have been motivated to use an oxidizing agent such as chlorinated isocyanurate with the expectation of obtaining a composition for the treatment of warts because (i) chlorinated isocyanurate on contact with water produces hypochlorous acid, and hypochlorous acid is more potent germicide than sodium hypochlorite for treatment of microbial diseases.

One of ordinary skill in the art would have been motivated to use oxidizing agent comprising sodium isocyanurate entrapped in the polymer with the expectation of obtaining a pharmaceutical composition that allows the sustained release of oxidizing agent sodium isocyanurate over extended period of time as instantly claimed for the treatment of skin ailment caused by human papilloma virus.

Therefore, claims 57-60, 65, 72, 75-85 are seen to be clearly obvious over the cited prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on 8 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

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PRIMARY EXAMINER

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4/14/05